

## **REMARKS**

Claims 1, 3, 4, 6-11, and 13-23 are pending in this application. Claims 1-23 are provisionally rejected on the grounds of obviousness-type double patenting over Application No. 11/376,983. Claims 1, 3, 4, and 6-23 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Thompson et al. in view of U.S. Patent Number 5,545,201 to Helland et al. Reconsideration is respectfully requested in light of the above claim amendments and the following remarks.

### **Double Patenting Rejection**

The Examiner has provisionally rejected the claims in this application for obviousness-type double patenting over Application Number 11/376,983. Because this is the earlier filed application of the two, a terminal disclaimer is not required and the application is allowable once the other rejections are overcome; a terminal disclaimer will be filed in Application Number 11/376,983 (if necessary) upon allowance of the claims in that application. MPEP §804(I)(B)(1).

### **Rejection Under 35 U.S.C. §103**

Claims 1, 3, 4, and 6-23 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Thompson et al. in view of U.S. Patent Number 5,545,201 to Helland et al. Reconsideration is requested.

Applicants' respectfully submit that the pending claims are not obvious in light of Thompson et al. and Helland based on the unexpected results achieved with Applicants' claimed invention. Unexpected results exist, and the claims are therefore not obvious, where the properties in the claimed invention and the prior art differ to such an extent that the difference is classified as a difference in kind, rather than one of degree. In re Waymouth, 499 F.2d 1273, 1276 (CCPA 1974). The title of the Thompson et al. patent is "System for Inducing Tachycardia Utilizing Near-Field T-Wave Sensing". At column 8, lines 22-26, Thompson et al. state "It is seen that this lead provides a distinctive signal which provides a significant improvement for very near-field T-wave detection which, e.g., is important for enhancing the tachy-inducing effectiveness of this invention." In addition, at column 8, lines 13-17, Thompson et al. state "By making the electrode spacing less than 1 mm, this electrode configuration provides excellent near

field sensing of cardiac signals; it can be used in the atrium for P-wave and atrial repolarization sensing, as well as in the ventricular [sic] for R-wave and T-wave sensing."

Therefore, Thompson et al. teach that a lead with a spacing of 1 millimeter or less between a distal, tip electrode and a ring electrode achieves improved T-wave sensing. In addition, as fully supported by the attached Declaration of Gene A. Bornzin, Ph.D, a lead such as that described by Thompson et al. achieves the results claimed in that patent, namely providing a sense signal that allows for detecting T-waves. Dr. Bornzin tested a lead having the specifications described by Thompson et al., and found no significant T-wave attenuation when the tip-to-ring spacing was reduced from 10 millimeters down to approximately 1.0 millimeter.

In contrast, as fully supported by the previously submitted Declaration of Yougandh Chitre, Applicants' claimed invention, by using a tissue-penetrating, helical tip electrode and an inter-electrode spacing of slightly greater than 1 millimeter, significantly attenuates T-wave signals, namely by approximately 75 percent compared to a control lead. This is clearly a difference in kind as opposed to a difference in degree; the prior art teaches improved detection of T-wave signals (and the actual lead tested by Dr. Bornzin does in fact provide a detectable T-wave signal), whereas Applicants' claimed invention significantly attenuates T-wave signals. Applicants' claimed invention achieves a completely different result, and therefore results in a difference in kind, which means there are unexpected results from Applicants' claimed lead such that the claimed lead is not obvious.

In addition, it is well settled that absence of an expected property which a claimed invention would have been expected to possess based on the teachings of the prior art is also evidence of nonobviousness. Ex parte Mead Johnson & Co., 227 USPQ 78 (Bd. Pat. App. & Inter. 1985). As the examiner states in the outstanding Office Action, he believes he has "found a lead that is structurally equivalent" to Applicants' claimed invention, and he further believes both leads would necessarily operate in the same manner. Because Applicants' claimed invention unexpectedly and significantly attenuates T-waves whereas the prior art teaches improved T-wave detection (and the actual lead does not significantly attenuate T-wave signals), there is an absence of an

expected property in the Applicants' claimed invention, further supporting Applicants' position that the claims are not obvious in light of the prior art.

Therefore, as has been clearly shown from the facts presented in the two submitted declarations, Applicants' claimed invention, by combining the features of a close inter-electrode spacing with a helix as the cathode electrode, significantly attenuates T-wave signals compared with a 10 millimeter spacing using the helix as the cathode electrode. In addition, a lead that uses a tip electrode for the cathode and a ring electrode for the anode does not significantly affect the amplitude of measured T-waves, regardless of whether the inter-electrode spacing is 10 millimeters or 1 millimeter. Applicants have clearly demonstrated, consistent with the teachings of Thompson et al., that inter-electrode spacing alone does not significantly attenuate T-waves, but that inter-electrode spacing combined with the use of a helix electrode achieves the unexpected result called for in Applicants' pending claims. The results achieved by Applicants' claimed invention are both unexpected and significant. Accordingly, it is respectfully submitted that the pending claims are nonobvious over the prior art.

**Conclusion**

In light of the above remarks and the declarations of Yougandh Chitre and Gene A. Bornzin, Ph.D, it is respectfully submitted that the application is in condition for allowance, and a notice of allowance is requested.

Respectfully submitted,

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